

MINUTES

UTAH ONLINE PRESCRIBING, DISPENSING AND FACILITATION LICENSING BOARD MEETING

June 7, 2011

**Room 474 – 4th Floor – 9:00 A.M.
Heber Wells Building
Salt Lake City, UT 84111**

CONVENED: 9:00 A.M.

ADJOURNED: 11:07 A.M.

Bureau Manager:
Board Secretary:

Noel Taxin
Karen McCall

Board Members Present:

Mark N. Bair, MD, Chairperson
Lt. Michael Ross
Peter L. Ax
Kathleen Littlefield, R.Ph.
Jennifer R. Korb
Roger Fitzpatrick, R. Ph.

Board Members Absent:

John W. Bachman, MD

Guests:

Kevin Marino, Attorney
Bill Stilling, Attorney
Brian Ackley, KwikMed IT

DOPL Staff Present:

Karl Perry, Assistant Attorney General
Joyce McStotts, Licensing Specialist
Peter Bresko, Licensing Specialist

TOPICS FOR DISCUSSION

DECISIONS AND RECOMMENDATIONS

ADMINISTRATIVE BUSINESS:

MINUTES:

The minutes from the April 12, 2011 Board meeting were read.

Ms. Littlefield made a motion to approve the minutes with minor revisions. Ms. Korb seconded the motion. The Board vote was unanimous.

APPOINTMENTS:

Clarification of Audit Review

Ms. Taxin explained that the Board had requested the audits be reviewed by the Board which is not the normal process for auditing of the professions/occupations of the Division due to the potential conflicts that may arise. She explained Secure Medical, Inc. has not yet been licensed long enough to conduct an audit so the Board will review the January and April audits for KwikMed only.

Ms. Taxin suggested the first few audits be reviewed by the Board as an educational training for KwikMed, Secure Medical, Inc. and the Board/Division to allow for feedback to make any necessary changes and understand the expectations/requirements. She stated in the future if there continues to be concerns then Investigations will need to be involved and the Board will not be involved in the audit as their responsibility is to act as a jury if there should be a hearing.

Ms. Taxin explained that she and Ms. McStotts developed an audit form and Ms. McStotts conducted the January and April audits for KwikMed. She stated it will be helpful to see the Secure Medical, Inc. audit for comparison as there may be different things each company needs to adjust.

Ms. Taxin suggested she and the Board hold off on expanding the Rules regarding the audits in order to have time to get a feel for what should be included.

Dr. Bair clarified the first few audits will be for training purposes and nothing will be referred to Investigations.

Ms. Taxin responded yes. She stated the concerns and issues pointed out today are for educational purposes but if they continue then she will need to involve Investigations.

Mr. Stilling asked if the Division is following GRAMA requirements by allowing the Board to review the audit.

Ms. Taxin responded she has tried to determine if the audit is public or private. She stated this is a new profession and the Division may need to add additional language to the GRAMA classifications by Rule.

Mr. Perry remarked he believes the audit is private and protected.

Mr. Fitzpatrick asked if the Board would potentially discuss patient medical information.

Ms. Taxin responded there were 20 files audited and the Board does not need to discuss specific patients or names.

Dr. Bair commented as long as the Board is not discussing specific patients or mentioning names he believes the Board may hear the audit presentation.

Mr. Stilling commented the communications must be only the minimum for the Board to obtain the information. He stated the Board could discuss treatment, payment and authorizations.

Ms. Taxin responded there is no need for Board members to discuss names, ID numbers or addresses. She stated the Division and Board members are also protected under HIPPA.

Ms. Taxin suggested Ms. McStotts present the audits.

9:20 am

KwikMed January 15, 2011 Audit Review

Ms. McStotts presented the January 15, 2011 audit.

Ms. McStotts questioned the following items:

1. She was able to pull the Utah patients only;
2. She was unable to pull random information;
3. She was unable to sort information by gender, drug or individual;
4. She was unable to locate the Physician summary or notes regarding prescriptions;
5. She asked if the CSR is entering notes instead

- of the Physician;
6. Ms. McStotts asked how to access information not listed or pulled into the offered information;
 7. She stated there was a list of 5 Physicians who are not licensed in Utah who had been prescribing and a Utah Pharmacy filling the orders;
 8. She asked how a male who has had a vasectomy or a female who has had a hysterectomy could receive the drug Ella;
 9. She asked why a prescription was issued for a drug that may not have been medically required, why there were no Physician notes regarding prescribing this medication and why were there not additional branching questions to determine appropriateness;
 10. She asked why one prescription was faxed to KwikMed instead of being issued through the branching questionnaire and questioned if the Utah Pharmacy was used; and
 11. Ms. McStotts asked how are the answers on the branching questionnaire evaluated to ensure the medication is required, what is considered to be dysfunction, what level of dysfunction actually requires medication, are emotional issues, depression, partner issues or other contributing factors evaluated or addressed and how are secondary issues evaluated.

Ms. McStotts explained she contacted Mr. Ackley who graciously walked her through some of the process and answered many of her questions and corrected some of the deficiencies.

KwikMed April 15, 2011 Audit Review

Ms. McStotts then presented the April 15, 2011 audit.

Ms. McStotts stated some of the program areas she needed to review had been changed and she could no longer get some information.

She stated she questioned the following items:

1. She stated the majority of her previous concerns had not yet been addressed;

2. She stated she needs access to all drugs prescribed and received by patients;
3. She stated she needs access to review Physician notes;
4. Ms. McStotts questioned how she can access random information not listed or pulled into the audit;
5. She stated the program was changed for listing the Physicians not licensed in Utah;
6. She asked how address errors are resolved or corrected;
7. She asked how two males could apply for and possibly receive prescriptions for Ella;
8. Ms. McStotts stated the number of prescriptions approved and the number listed do not match;
9. She voiced concern in regard to the person completing the branching questionnaire not being the person who will take the drug;
10. She questioned how the age of the patient is considered with secondary issues such as taking additional medications, medical recommendations, dosages, etc.; and
11. Ms. McStotts voiced concern about emails addressing international patients.

Mr. Ax requested that an active mock demonstration be presented.

Ms. Taxin asked if the Board could review the information if names were brought up.

Mr. Ax responded the Board should not review addresses and no patient information should be distributed to the Board.

Mr. Stilling responded private information cannot be viewed by the public.

Mr. Ax commented the public members on the Board could not review the information.

Ms. Taxin reminded the Board that the public members are Board members and bound by the same regulations as licensees on the Board.

Mr. Ax stated members of the public in attendance could take notes.

Mr. Stilling responded no one but the Board should see private information and the names should be withheld from the public. He suggested the names and addresses be redacted in the future.

Dr. Bair suggested the Board discuss without reviewing actual file information.

Ms. Taxin stated she noticed some information was in Spanish.

Mr. Ackley responded Ms. Taxin should also be able to review the information in English.

Mr. Ax again suggested the Board review an active demonstration as he has not been advised of the criteria used for the audit.

Dr. Bair suggested the review continue.

Ms. Taxin responded the criteria were taken from the requirements in the Online Prescribing, Dispensing and Facilitation Practice Act and Rule, the Pharmacy Practice Act and Rule, the Medical Practice Act and Rule as well as the Osteopathic Physician Act and Rule.

Ms. McStotts continued and asked for clarification regarding the discrepancy of prescriptions approved and filled. She stated she also noticed responses that appear to be standard and information with no punctuation or correct spelling.

Ms. Littlefield responded the discrepancy is not uncommon as patients decide not to fill prescriptions and that could account for the 204 prescriptions unaccounted for.

Mr. Ax asked how he might help educate the Board in regard to the information Ms. McStotts views for the audit.

Dr. Bair asked if KwikMed conducts an internal audit.

Mr. Ax responded KwikMed does not have an outside peer review but they do conduct an internal audit. He stated KwikMed has a pick list of standardized responses for the Physician to choose from and all audited responses have been appropriate with correct punctuation and spelling. He stated the Physician might write something to the patient and that note is appropriate.

Ms. Taxin commented that Mr. Ax and Mr. Ackley may review the information Ms. McStotts printed out to see what she has reported.

Dr. Bair asked how Ella was prescribed to a male.

Mr. Ax responded it is not.

Ms. Taxin stated the Division has the printed documentation if Mr. Ax wants to review it.

Mr. Perry commented Mr. Ax had explained credit card payments would be cross referenced so the person purchasing the medications would be the person taking the medications. He asked how the medications are being approved when the patient who will take the medication did not complete the branching questionnaire.

Mr. Ax responded he will check the records.

Ms. McStotts asked how an ED medication was prescribed to a 71 year old male who indicated he is healthy but has ED.

Dr. Bair commented ED usually has an underlying cause. He asked if there is a time when additional questions should be asked in the branching questionnaire.

Mr. Ax stated that the Division has access to a lot of information. He stated Ms. McStotts reviewed

the information and requested some changes, which KwikMed made and now she is saying these are concerns.

Ms. Taxin reminded Mr. Ax that he requested all application and audit information be brought before the Board for review.

Ms. McStotts then referred to a 30 year old patient who has been dissatisfied with the ED medications. She asked if there is an expanded set of questions to determine if something else is going on and if the Physician should be reviewing and commenting on the review and/or issues.

Mr. Ax requested the file number for him to review.

Dr. Bair suggested the specific file information be provided after the meeting as it does not affect the Board's discussion but KwikMed needs to be provided the information in order to correct their system.

Mr. Marino commented he has been unable to locate specific audit information requirements by Law or Rule.

Ms. Taxin responded the information is found in the Law under 58-83-308 and the Rule in R156-83-308.

Dr. Bair reminded the Board that this discussion is for education purposes only and to assist with determining what additional specifics should be in the Law and Rule. He stated it is a concern to hear inappropriate drugs have been inappropriately prescribed.

Mr. Marino suggested the audits be between the licensee and the Division only, rather than being reviewed at a Board meeting.

Ms. Taxin responded that usually audits are private but Mr. Ax had requested the Board review the audits as he stated they should be making the decisions and not

the Division.

Mr. Ax responded KwikMed was given a deadline for the audit and provided the information in advance. He stated KwikMed requested Ms. Taxin to review the information and report back if there were any issues. Mr. Ax stated Ms. McStotts got back to KwikMed and the requested changes were made.

Ms. Taxin agreed with Mr. Ax and then stated after the changes were made from the first audit the Board met and Mr. Ax requested the audits be reviewed by the Board.

Mr. Ax voiced his concern in discussing the issues with the Board. He stated he believed the best way to review the issues is to have a live demonstration.

Ms. Taxin responded a live mock demonstration is not the same as reviewing actual patient files.

Dr. Bair suggested the meeting move on. He asked if the Board members were concerned about inappropriate drugs being prescribed and from an audit standpoint and standard of care is it inappropriate to prescribe morning after drugs to males. He then stated anytime something raises a question there should be a specific Physician note to address the issues.

Mr. Ax responded the Online Prescribing is not a traditional situation. He stated the patient has completed a great amount of work on the front end in answering the branching questionnaire and if he were the MD he would look at a healthy male with no health issues and wonder why he should make a note in the file.

Dr. Bair responded a simple telephone call to a dissatisfied male and then making a note would address the issue.

Mr. Marino commented it is clear the Board needs a framework of specifics that should be included in

the audits. He stated the audit process is only one process of overseeing this profession. He stated the Division did the audit and should contact KwikMed to request what is seen in the backend. He stated Mr. Ax requested the review be at the Board level and at the end of the day there should be an agreement to specific issues and a template established that would be used for the audits.

Dr. Bair responded Mr. Marino is correct but this is a new profession. He stated he believes Ms. Taxin's approach has been good and informs the Board of what was reviewed. He stated the Board is in the process of establishing the needed framework for the audit review.

Ms. Taxin again stated some of the information for the audit deficiencies are found in the Medical Practice Act and the Pharmacy Practice Act. She stated the Division needs to know what issues are of concern to the Board.

Ms. Littlefield commented the audit was amazing. She stated if Ms. McStotts had been able to review Physician notes on the 71 year old male then that may not have been an issue. Ms. Littlefield voiced concern in regard to two males receiving Ella as there should not be accommodations online for males to receive Ella for female partners.

Dr. Bair stated the ability to prescribe for a partner is now available in Utah but the females name must be on the prescription, i.e.: he cannot write a prescription for John Smith for Stephanie Smith.

Ms. McStotts stated the female may not have filled out the section of other prescriptions she may be taking and the drug interactions may have not been addressed.

Mr. Ax responded there is protocol that the female should have had some interaction. He stated a KwikMed Physician would reject the prescription request if it is male and contact the patient. He

stated customer service would put notes in the file.

Dr. Bair stated the female should fill out the questionnaire for herself to receive the medication. He stated Mr. Ax knows what should happen but clearly in the two cases audited the males were given Ella.

Mr. Ax responded KwikMed will need to correct the system to assure inappropriate medications are not prescribed to inappropriate patients. He stated he will need to review the Medical Practice Act and Pharmacy Practice Act to be sure they are abiding by these requirements.

Ms. Taxin referred Mr. Ax to the Division website and to the AMA Code of Ethics for the regulations.

Mr. Perry stated the Physicians for KwikMed and Secure Medical, Inc. will be held to specific standards set forth in their practice act.

Mr. Ax responded the Physicians not licensed in Utah are licensed in other States and they would not be prescribing in Utah.

Ms. Taxin asked if they are filling the prescriptions through a Utah Pharmacy.

Mr. Ax responded yes.

Ms. Taxin asked that KwikMed identify the Physicians, where they are licensed, what and where medications are being dispensed.

Mr. Ackley stated not just anyone is allowed to query their database but they can do better to make the information visible to the Division audits.

Mr. Fitzpatrick commented this is a learning experience for the Board, applicants, visitors and the Division. He asked if a hard stop needs to be on the field for the Physicians so it is not overlooked. He stated it will be helpful to have standards in place for anyone else applying for a license so they

know what is expected. He stated the audits are helpful so the Board can expand the criteria regarding information to be viewed. Mr. Fitzpatrick stated he believes the Board and KwikMed have learned a lot today regarding areas in question. He stated he would like the main criteria for an audit to be expanded and put in Rule for future audits. Mr. Fitzpatrick stated Ms. McStotts has presented information that may need further clarification and Mr. Ackley can go back to KwikMed and revise their program to allow the Division more access. He stated the Board is trying to protect the public and Ms. McStotts audited 20 files out of 14,732 branching questionnaire and found several issues of concern. He asked how many additional issues might there be that need to be reviewed. He stated the Board needed to review the audit information in order to make some decisions and when the Division sits down with KwikMed to review the specifics then KwikMed can make the needed changes and hopefully there has been no damage done to patients. He stated it is important for the Board to start the process of expanding Rules to outline audit requirements. He stated if there continues to be issues then the Board should be concerned if the public is being protected but the process is important.

Mr. Ax commented all KwikMed intentions are positive. He stated Ms. McStotts did an outstanding job in obtaining the details and the lessons have been learned. He voiced appreciation in Mr. Fitzpatrick's suggestion to iron out the issues without taking them to the Board.

Mr. Fitzpatrick stated he sat on the Pharmacy Board and met with probationers on that Board. He stated Board members have no idea what the Division has done prior to a practitioner meeting with the Board for probation. He stated this Board is going through a similar process in developing criteria for future applicants and future audits.

Ms. Taxin responded the Online licensees are companies and they need to take responsibility for

following the Laws and Rules. She stated both companies have bright individuals who can assist with developing the specifics the Board and Division need. She stated she believes feedback makes better practitioners and Mr. Ax has stated he believes in the process. She stated she believes it is better to find the issues and correct them internally versus having others find them and call the Division.

Dr. Bair requested Ms. McStotts create a summary audit list in addition to her full audit and create specific categories in a list of eight to ten things she is specifically looking for and other areas the Board has concerns about and then provide it to the Board prior to the next meeting.

Mr. Perry suggested Ms. McStotts also identify the prescriptions written but not filled as it was unclear where those went.

Dr. Bair requested discussion regarding what constitutes an adequate medical history and criteria for drugs to be added.

Ms. Littlefield suggested when Ms. McStotts audits that she remove the name and create patient A, B, etc. if she has specific patient information to be reviewed.

Mr. Stilling suggested the Facilitators assist with redacting. He stated if Ms. McStotts identifies ten specific charts he and Mr. Korsunsky could go through and do random assigning of numbers and redact information. He stated he would then give a copy to the Division to copy for the Board.

Dr. Bair concluded the audit discussion.

DISCUSSION ITEMS:

Rules

Ms. Taxin stated the next Board meeting is scheduled for September 20, 2011. She assigned the Board to read the Law and Rule and to draft their ideas for criteria for audits and new drugs. She requested they email the information to her to review and she stated

she will make copies for all Board members for the meeting.

Mr. Fitzpatrick suggested the Board also include criteria for the assessment tool/branching questionnaire.

Audit Dates and Board Meeting Dates

Ms. Taxin stated there are meetings scheduled through December. She asked if the Board would like the 2012 meetings to be scheduled just after the audits.

The Board responded yes.

Mr. Stilling stated he believed the Division was not going to bring detailed audits to the Board to review.

Ms. Taxin responded Mr. Stilling is correct in the future but for now the Board will be reviewing audit information.

CORRESPONDENCE:

Joel Korsunsky Letter requesting consideration for Staxyn to be an approved Online Medication

The Board reviewed Mr. Korsunsky's request.

Mr. Fitzpatrick commented Staxyn should already be approved as it is the specific brand name of the approved generic legend drug. He stated it was for this reason that the generic names were put in the Rules so each brand name drug does not have to come before the Board.

Mr. Ax asked if Board members can suggest drugs to be listed.

Ms. Taxin responded yes.

NEXT MEETING SCHEDULED FOR:

September 20, 2011

ADJOURN:

The time is 11:07 am and the Board meeting is adjourned.

Note: These minutes are not intended to be a verbatim transcript but are intended to record the significant features of the business conducted in this meeting. Discussed items are not necessarily shown in the chronological order they occurred.

September 20, 2011
Date Approved

Mark N. Bair, MD
Chairperson, Utah Online Prescribing, Dispensing and
Facilitation Licensing Board

June 23, 2011
Date Approved

(ss) Noel Taxin
Bureau Manager, Division of Occupational &
Professional Licensing